510(K) SUMMARY OF SAFETY AND EFFECTIVENESS
GAMBRO WRO 300 WATER PURIFICATION SYSTEM FOR HEMODIALYSIS

510(k) Number: K042797

MAR 9 - 2005

A. Submitter's Information

Name:	Gambro Renal Products
Address:	10810 West Collins Avenue Lakewood, Colorado 80215 USA
Phone:	303-542-5075
Fax:	303-542-5138
Contact:	Rod J. Rylands Quality and Regulatory Director Gambro Renal Products International Sales

B. Device Information

Classification name:	Water Purification System For Hemodialysis [21 CFR 876.5665]
Common or usual name:	Water Purification System For Hemodialysis
Proprietary Name(s):	WRO 300 Water Purification System For Hemodialysis
Product Code Classification Panel:	FIP/Gastroenterology-Urology
Device Classification:	Class II per 21 CFR 876.5665

C. Predicate Device Information

Predicate Device Name:	Gambro WRO 10-01
FDA Clearance:	K811678

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D. Substantial Equivalence

The proposed Gambro WRO 300 Water Purification System is substantially equivalent to the Gambro WRO 10-01 Water Purification System. The current Gambro WRO 10-01 Water Purification System has been cleared for marketing / sale in the United States under 510K Notification – K811678.

E. Device Description

The Gambro WRO 300 water purification unit is designed to be used as a dialysis accessory device to produce water used to prepare and dilute dialysis concentrate to form dialysis fluid by using the reverse osmosis concept. It is intended for use in conjunction with one dialysis machine, provided that the input flow and pressure demands correspond to the output of the WRO 300 unit.

F. Indications For Use

The Gambro WRO 300 Water Purification System is intended to be used as a dialysis accessory device in conjunction with one dialysis machine to produce water used to prepare and dilute dialysis concentrate to form dialysis fluid by using the reverse osmosis concept.

G. Summary of Non-Clinical Tests Submitted

The Gambro WRO 300 water purification unit is designed to be used as a dialysis accessory device to produce water used to prepare and dilute dialysis concentrate to form dialysis fluid by using the reverse osmosis concept. It is intended for use in conjunction with one dialysis machine, provided that the input flow and pressure demands correspond to the output of the WRO 300 unit. Testing verified that the reverse osmosis method used in the WRO 300 produces purified water for use in Dialysis.

H. Summary of Clinical Tests Submitted - Not Applicable

7 October 2004

Rod J. Rylands
Quality and Regulatory Director
Gambro Renal Products International Sales

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

MAR 9 - 2005

Mr. Thomas B. Dowell
Regulatory Project Manager
Gambro® Renal Products
10810 W. Collins Avenue
LAKEWOOD CO 80215

Re: K042797
Trade/Device Name: Gambro WRO 300 Water Purification System for Hemodialysis
Regulation Number: 21 CFR §876.5665
Regulation Name: Water purification system for hemodialysis
Regulatory Class: II
Product Code: 78 FIP
Dated: March 2, 2005
Received: March 4, 2005

Dear Mr. Dowell:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (Premarket Approval), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

This letter will allow you to begin marketing your device as described in your Section 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Office of Compliance at one of the following numbers, based on the regulation number at the top of this letter:

21 CFR 876.xxxx	(Gastroenterology/Renal/Urology)	240-276-0115
21 CFR 884.xxxx	(Obstetrics/Gynecology)	240-276-0115
21 CFR 892.xxxx	(Radiology)	240-276-0120
Other		240-276-0100

Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21 CFR 807.97). You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 443-6597 or at its Internet address http://www.fda.gov/cdrh/industry/support/index.html.

Sincerely yours,

Nancy C. Brogdon

Nancy C. Brogdon
Director, Division of Reproductive,
Abdominal, and Radiological Devices
Office of Device Evaluation
Center for Devices and Radiological Health

Enclosure

Indications for Use Statement

510(k) Number (if known) K042797

Device Name Gambro WRO 300 Water Purification System

Indications for Use

The Gambro WRO 300 Water Purification System is intended to be used as a dialysis accessory device in conjunction with one dialysis machine to produce water used to prepare and dilute dialysis concentrate to form dialysis fluid by using the reverse osmosis concept.

PLEASE DO NOT WRITE BELOW THIS LINE - CONTINUE ON ANOTHER PAGE IF NEEDED

Concurrence of CDRH, Office of Device Evaluation (ODE)

Prescription Use ✓ OR Over-The-Counter Use _____
(Per 21 CFR 801. 109)

Nancy C Brogdon
(Division Sign-Off)
Division of Reproductive, Abdominal, and Radiological Devices
510(k) Number K042797